United States
Environmental Protection
Agency

Office of Prevention, Pesticides
and Toxic Substances
(7501C)

Pesticide Fact Sheet

Name of Chemical: **Tralkoxydim**
Reason for Issuance: **Conditional Registration**
Date Issued: **December 4, 1998**

DESCRIPTION OF CHEMICAL

Generic Name:	2-(cyclohexen-1-one, 2-[1-(ethoxyimino)propyl]-3-hydroxy-5-(2,4,6-trimethylphenyl)-(9Cl)
Common Name:	tralkoxydim
Trade Names:	Tralkoxydim Technical Achieve 40DG Herbicide Achieve 80DG Herbicide
EPA Chemical Code:	121000
Chemical Abstracts Service (CAS) Number:	87820-88-0
Year of Initial Registration:	1998
Pesticide Type:	Herbicide
Chemical Family:	Cyclohexanedione herbicides
U.S. and Foreign Producers:	Zeneca Ag Products 1800 Concord Pike P.O. Box 15458 Wilmington, DE 19850-5458

USE PATTERNS AND FORMULATIONS

Tralkoxydim is applied to actively growing weeds in wheat and barley to control wild oats, green foxtail, yellow foxtail, annual ryegrass (Italian) and persian darnel. It will be formulated as a 40% dry granular [Achieve 40 DG Herbicide] and 80% dry granular [Achieve 80 DG Herbicide]. Achieve 40 DG Herbicide will be applied by ground and aerial application at 0.44 to 0.60 pounds (lb.) per acre (A)[0.18 to 0.24 pounds active ingredient (ai)/A]. Achieve 80 DG Herbicide will be applied by ground and aerial application at 0.22 to 0.30 lb/A. The maximum seasonal application rate is 0.25 lb tralkoxydim ai per acre per year.

Tralkoxydim Technical, wet paste, is a 81% manufacturing use product.

SCIENCE FINDINGS

SUMMARY SCIENCE STATEMENTS

Adequate chemistry, toxicological, ecological effects, and environmental fate data have been submitted and reviewed to support the conditional registration of Achieve 40DG Herbicide and Achieve 80 DG Herbicide on wheat and barley and Tralkoxydim Technical, wet paste, as a manufacturing use pesticide until February 28, 2003.

The technical tralkoxydim product is classified in toxicity category III [CAUTION] based on acute dermal toxicity, acute dermal toxicity, acute inhalation toxicity, and primary eye irritation studies. The Achieve 40 DG and 80 DG formulated end use products are classified in toxicity category III [CAUTION] based on the acute oral toxicity, acute dermal toxicity, and primary eye irritation studies.

Tralkoxydim was shown to be negative in assays for gene mutation in bacteria, forward gene mutation in mouse lymphoma cells in culture, chromosome damage in human lymphocyte cells, for DNA damage in rat hepatocytes, and for chromosome damage *in*

vivo mouse micronuclei.

In the rat the No Observed Adverse Effect Level (NOAEL) for maternal toxicity and developmental toxicity is 30 milligrams / kilogram(mg/kg)/day. In the rabbit, the NOAEL for maternal toxicity and developmental toxicity was 200 mg/kg/day. In a three-generation rat reproduction study, the parental systemic NOAEL was 20 mg/kg/day and no reproductive toxicity was observed. Developmental toxicity did not occur at doses below those causing maternal toxicity.

In a 90-day rat feeding study the NOAEL was 20.5 mg/kg/day for males and 23.0 mg/kg/day for females. In a 90-day hamster feeding study the NOAEL was 328 mg/kg/day. In a 90-day dog dietary study the NOAEL was 0.5 mg/kg/day. In a 21-day rat dermal study the NOAEL was 1000 mg/kg/day, the highest dose tested [HDT]. In a 1-year dog chronic feeding study, the NOAEL was 0.5 mg/kg/day and the Lowest Observed Adverse Effect Level (LOAEL) was 5 mg/kg/day based on changes in liver function and morphology in males.

In the rat chronic feeding / carcinogenicity study the systemic toxicity NOAEL was 23.1 mg/kg/day in males and 30.1 mg/kg/day in females and the systemic toxicity LOAEL was 117.9 mg/kg/day in males and 162.8 mg/kg/day in females based on decreased body weight gain, decreased food consumption, increased liver weights, and increased hepatic clear cell areas and increased ALT levels in females. Based on the incidence of Leydig cell tumors in the testes, tralkoxydim was considered to have a positive carcinogenic response.

Tralkoxydim is classified as a "likely to be a human carcinogen" based on 1) the occurrence of rat benign Leydig cell tumors at all dose levels, 2) the lack of an acceptable carcinogenicity study in a second species, and 3) the relevance of the testicular tumors to human exposure can not be discounted.

Based on the results of the hamster and rat metabolism studies, tralkoxydim was readily absorbed and excreted within 24 and 48 hours after dosing, respectively. In hamsters, the metabolic profile in urine was similar for males and females; no unchanged tralkoxydim was detected and two major metabolites were

identified: tralkoxydim acid and tralkoxydim acid oxazole. The metabolic profile in the urine of rats included two additional metabolites, tralkoxydim alcohol and tralkoxydim diol.

The chronic Reference Dose (RfD) for Tralkoxydim is 0.005 mg/kg/day. This value is based on the NOAEL of 0.5 mg/kg/day in the dog chronic feeding study with a 100-fold safety factor to account for interspecies extrapolation (10x) and for intraspecies variability (10x).

A DEEM chronic exposure analysis was conducted using tolerance levels for wheat and barley and assuming that 100 percent of the crop is treated to estimate dietary exposure for the general population and 22 subgroups. The chronic analysis showed that exposures from tolerance level residues in or on wheat and barley for children 1-6 years old (the subgroup with the highest exposure) would be 1.4% of the Reference Dose (RfD). The exposure for the general U.S. population would be less than 1% of the RfD.

An acute dietary risk assessment is required for tralkoxydim based on the NOAEL of 30 mg/kg/day from the rat developmental study. The acute dietary analysis using the DEEM computer program estimates that the distribution of single-day exposures utilizes 0.02 percent of acute RfD.

A lifetime dietary carcinogenicity exposure analysis was conducted for tralkoxydim using the proposed tolerances along with the assumption of 100% of the crop treated and a Q* of 1.68 x 10^{-2} $(mg/kg/day)^{-1}$. A lifetime risk exposure analysis was also conducted using the DEEM computer analysis. The estimated cancer risk (5 x 10^{-7}) is less than the level that the Agency usually considers for negligible cancer risk estimates.

Drinking water acute estimated environmental concentration (EECs) for surface water (parent tralkoxydim) was calculated by PRIZM-EXAMS computer models to be an average of 4.3 parts per billion (ppb)and 0.528 ppb for chronic EEC. The EEC for ground water based on the computer model SCI-GROW2 were calculated to be an average of 0.016 ppb. The drinking water level of comparison (DWLOC) for acute exposure to tralkoxydim in drinking water calculated for females 13+ years old was 9000 ppb. EPA's acute drinking water level of comparison is well above the estimated

exposures for tralkoxydim in water for the subgroup of concern.

The drinking water level of comparison (DWLOC) for chronic exposure to tralkoxydim in drinking water calculated for U.S. population was 150 ppb and for children (1 - 6 years old) the DWLOC was 50 ppb. EPA's chronic drinking water level of comparison for the U.S. population and the subgroup of concern is above the estimated exposures for tralkoxydim in water of 0.528 ppb for surface water and 0.016 ppb for groundwater.

A DWLOC for cancer was calculated as 1 ppb. The EEC in surface water and groundwater for tralkoxydim residues are 0.528 ppb and 0.016 ppb, respectively. The model exposure estimates are less than the cancer DWLOC.

EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to tralkoxydim residues. The nature of the residue in plants is adequately understood for the purposes of this time-limited tolerance. Based on the results of animal metabolism studies, it is unlikely that significant residues would occur in secondary animal commodities from this use.

Tolerances are established for the residues of the herbicide, tralkoxydim, 2-(Cyclohexen-1-one, 2-[1-(ethoxyimino)propyl]-3-hydroxy-5-(2,4,6-trimethylphenyl)-(9Cl) in or on the raw agricultural commodities: barley grain, barley hay, wheat grain and wheat hay at 0.02 ppm, and barley straw, wheat forage and wheat straw at 0.05 ppm. These time-limited tolerances will expire on February 28, 2003.

EPA is currently developing an screening, testing program and a priority setting scheme for endocrine disrupters.

Tralkoxydim hydrolysis is pH dependent with calculated half-lives of 6.3 days at pH 5, 114 days at pH 7 and 1,594 days at pH 9. Tralkoxydim is not persistent to photodegradation in water with calculated half-life was 19.3 days. On soil surfaces, tralkoxydim rapidly photolyzed with a corrected half-life of 2.4 days.

Tralkoxydim rapidly degraded in the aerobic United Kingdom soils. The major degradates were tralkoxydim acid (Compound 8) and Compound 17. Compound 8 reached a maximum concentration of 12.5% of by 7-15 days posttreatment and declined to non-

detectable concentrations by 30-65 days posttreatment. Compound 17 increased to 17.2% by 3-15 days and declined to 1 - 2.9% by the end of the study (94 days). For anaerobic aquatic metabolism tralkoxydim half-lives ranged from 47 to 115 days, and were not used in risk assessment because of this variation. Soil adsorption/desorption data indicate that tralkoxydim and its degradates are very mobile in most of the tested soils. In supplemental field dissipations studies in Illinois, Montana, Washington and Canada, the parent compound dissipated rapidly with half-lives from < 1 to 35 days.

Tralkoxydim residues bioaccumulation was relatively low in Bluegill Sunfish exposed in a flow-through system for 28 days.

Based on PRIZM-EXAMS and SCI-GROW2 computer models, concentrations of tralkoxydim in surface water and ground water are expected to be 0.528 µg/L and 0.016 µg/L, respectively.

Tralkoxydim was shown to be practically non-toxic to birds, slightly toxic to small mammals, practically non-toxic to bees and other beneficial insects, and practically non-toxic to fresh water invertebrates. Adverse effects to surrounding plant communities may occur if Tralkoxydim drifts off the treatment site. Environmental Hazard precautionary statements are required.

TECHNICAL CHEMICAL CHARACTERISTICS

Empirical Formula:	$C_{20}H_{27}O_3N$
Molecular Weight:	329.4
Color:	Off white to pale pink
Physical State:	solid
Odor:	Faint burnt odor
Melting Point:	106°C
Density:	1.16 g/cm^3 (dry)

	1.13 g/cm^3 (wet)
Solubility g/liter:	water - 6 mg/L (pH 5.2) 7 mg/L (pH 6.5) 8850 mg/L (pH 9.0) acetone - 89 g/L dichloromethane - >500 g/L ethyl acetate 110 g/L hexane - 18 g/L methanol - 25 g/L toluene - 213 g/L
Vapor Pressure:	1.6 x 10^{-5} mm Hg at 80° C 4.6 x 10^{-6} mm Hg at 70° C 2.4 x 10^{-6} mm Hg at 65° C 6.4 x 10^{-7} mm Hg at 55° C 3.2 x 10^{-7} mm Hg at 50° C 2.8 x 10^{-8} mm Hg at 30° C by extrapolation 3.2 x 10^{-9} mm Hg at 20° C by extrapolation
Dissociation Constant:	pKa = 4.3 (25° C; weak acid)
Octanol/Water partition coefficient:	Log P_{ow} = 2.1
pH:	5.3 at 22° C
Stability:	Stable at normal warehouse temperatures. Non-corrosive.

TOXICOLOGY CHARACTERISTICS

Achieve 50 WDG Herbicide
(Canadian End-Use Product)

Acute Oral Toxicity (rats):	LD50 Males > 5000 mg/kg LD50 Females 3220 mg/kg
Toxicity Category:	III

Acute Dermal Toxicity (rats):	LD50 > 2000 mg/kg
Toxicity Category:	III
Primary Eye Irritation (rabbits):	Moderate irritant
Toxicity Category:	III
Primary Skin Irritation (rabbits):	Slight erythema regressed within 24 hours
Toxicity Category:	IV
Dermal Sensitization (guinea pigs):	Non-sensitizer

Achieve 40 DG Herbicide

Acute Inhalation Toxicity (rats):	LC50 > 3.71 mg/l
Toxicity Category:	IV

Since Achieve 50 WDG and Achieve 40 DG are substantially similar, the studies conducted on Achieve 50 WDG will support Achieve 40 DG Herbicide.

Tralkoxydim Technical
(manufacturing use product)

Acute Oral Toxicity (rats):	LD50 Males 1258 mg/kg LD50 Females 934 mg/kg
Toxicity Category:	III

Acute Oral Toxicity (mice):	LD50 Males 1231 mg/kg LD50 Females 1100 mg/kg
Toxicity Category:	III
Acute Dermal Toxicity (rats):	LD50 > 2000 mg/kg
Toxicity Category:	III
Acute Inhalation Toxicity (rats):	LC50 > 0.9 mg/L
Toxicity Category:	III
Primary Eye Irritation (rabbits):	Mild conjunctivitis lasting for 3 days
Toxicity Category:	III
Primary Skin Irritation (rabbits):	Slight erythema/edema lasting for 2 to 3 days
Toxicity Category:	IV
Dermal Sensitization (guinea pigs):	Non-sensitizer

Since Achieve 80 WDG and Tralkoxydim Technical are substantially similar, the studies conducted on Tralkoxydim Technical will support Achieve 80 DG Herbicide.

90-day dietary

(rats):	NOAEL = 250 ppm [20.5 mg/kg/day for males and 23.0 mg/kg/day for females] LOAEL = 2500 ppm [204.8 mg/kg/day for males and 219.3 mg/kg/day for females] based on decreased food efficacy and minor hematologic changes.
90-day dietary (hamster):	NOAEL = 5000 ppm [328 mg/kg/day] LOAEL = 10,000 ppm [650 mg/kg/day] based on decreased body weight gains and increased liver weights in both sexes.
90-day dietary (dog):	NOAEL = 0.50 mg/kg/day LOAEL = 5 mg/kg/day based on increased liver weights in males and increases in APDM in males and females, indicating minimal hepatotoxicity.
21-day dermal (rats):	NOAEL = 1000 mg/kg/day the highest dose tested [HDT].
Developmental Toxicity (rabbit):	Maternal NOAEL = 20 mg/kg/day Maternal LOAEL = 100 mg/kg/day based on reduced food consumption. Developmental NOAEL = 20 mg/kg/day Developmental LOAEL = 100 mg/kg/day based on abortions and increases in late resorptions.
Developmental Toxicity (rat):	Maternal NOAEL = 30 mg/kg/day Maternal LOAEL = 200 mg/kg/day based on maternal mortality, reduced body weights, and reduced food consumption. Developmental NOAEL = 30 mg/kg/day Developmental LOAEL = 200 mg/kg/day based on reduced ossification of the centrum and

	hemicentrum, centrum bipartite, misshapen centra, and fused centra.
Three-Generation Reproduction (rat):	Parental Systemic NOAEL = 200 ppm [20 mg/kg/day] Parental Systemic LOAEL = 1000 ppm [100 mg/kg/day] based on reduced body weights and body weight gains in P, F_1 and F_2 females. No reproductive toxicity was observed. Developmental NOAEL = 200 ppm [20 mg/kg/day] Developmental LOAEL = 1000 ppm [100 mg/kg/day] based on decreased mean pup weights (F_{1a} and F_{3a}) and pup body weight gains (F_{2a}).
1 Year Chronic Feeding (dog):	NOAEL = 0.5 mg/kg/day LOAEL = 5 mg/kg/day based on changes in liver function and morphology in males.
Chronic Feeding/ Carcinogenicity (rat):	Systemic Toxicity NOAEL = 500 ppm [23.1 mg/kg/day in males and 30.1 mg/kg/day in females]. Systemic Toxicity LOAEL = 2500 ppm [117.9 mg/kg/day in males and 162.8 mg/kg/day in females] based on decreased body weight gain, decreased food consumption, increased liver weights, and increased hepatic clear cell areas and increased ALT levels in females. Based on the incidence of Leydig cell tumors in the testes, tralkoxydim was considered to have a positive carcinogenic response.
Carcinogenicity:	The Health Effects Division Cancer Assessment Review Committee has classified Tralkoxydim in accordance with the Agency's *Proposed Guidelines for Carcinogen Risk Assessment*

(April 10, 1996) as a "likely to be a human carcinogen". This classification is based on the following factors:

A. Occurrence of benign Leydig cell tumors at all dose levels with the incidences at the high dose exceeding the concurrent and historical control range.

B. Lack of an acceptable carcinogenicity study in a second species as required by Subdivision F Guidelines.

C. The relevance of the testicular tumors to human exposure cannot be discounted

Mutagenicity — Tralkoxydim was negative for mutagenic / genotoxic effects in a Gene mutation Ames Assay in bacteria, a forward gene mutation in mouse lymphoma cells in culture, chromosome damage/*In vitro* assay in human lymphocyte cells, DNA damage repair *in vivo* assay in rat hepatocytes, and chromosome damage *in vivo* mouse micronuclei.

Metabolism: Based on the results of the hamster and rat metabolism studies, tralkoxydim was readily absorbed and excreted within 24 and 48 hours after dosing, respectively. In hamsters, the metabolic profile in urine was similar for males and females; no unchanged tralkoxydim was detected and two major metabolites were identified: tralkoxydim acid and tralkoxydim acid oxazole. The metabolic profile in the urine of rats included two additional metabolites, tralkoxydim alcohol and tralkoxydim diol.

Special Studies: Several mechanistic studies and subchronic feeding studies were submitted to support the selection of hamster in preference to the mouse in assessing the carcinogenic potential

of tralkoxydim. The submitted data indicate that of all the species tested only the mouse is susceptible to porphydrin accumulation in the liver following treatment with tralkoxydim. The mouse is considered an inappropriate species to use for carcinogenicity testing of tralkoxydim because of its distinctive method of metabolism. However, the submitted hamster cancer study was unacceptable owing to unacceptably high mortality in the females. An acceptable second species carcinogenicity study is required.

ECOLOGICAL CHARACTERISTICS

Avian Acute Toxicity:

Mallard Duck:	LD_{50} > 3020 mg/kg

Avian Dietary Toxicity:

Bobwhite Quail:	5-day LC_{50} = 5995 ppm ai
Mallard Duck:	5-day LC_{50} > 7400 ppm ai

Avian Reproduction:

Bobwhite Quail*:	No Observed Adverse Effect Concentration (NOAEC) > 150 ppm
Mallard Duck*:	NOAEC > 150 ppm

*Supplemental studies since Lowest Observed Adverse Effect Concentration (LOAEC) was not determined.

Freshwater Fish Acute Toxicity:

Bluegill Sunfish	LC_{50} was not determined. > 7.50 ppm highest level tested.
Rainbow Trout:	LC_{50} was not determined. > 7.50 ppm highest level tested.

Freshwater Invertebrate Toxicity:

Daphnia magna	48-hour EC50 > 174 ppm - Technical Grade Active Ingredient (TGAI)
Daphnia magna	48-hour EC50 = 2.4 ppm - Typical End-Use Product (TEP)

Freshwater Invertebrate Life-Cycle Toxicity:

Daphnia magna	NOAEC = 2.1 ppm ai LOAEC = 4.2 ppm ai based reproduction

Non-Target Insects Toxicity:

Honey Bee Acute Contact	LD50 > 100 µg ai/bee - Technical LD50 > 50 µg ai/bee - Formulation

Seedling Emergence and Vegetative Vigor for Tralkoxydim Technical (Tier II)

Seedling Emergence:

Dicot - Cabbage	EC_{25} > 0.23 (lb ai/acre) - shoot dry weight
Dicot - Cucumber	EC_{25} > 0.23 (lb ai/acre) - shoot dry weight
Dicot - Lettuce	EC_{25} > 0.23 (lb ai/acre) - shoot dry weight
Dicot - Soybean	EC_{25} > 0.23 (lb ai/acre) - shoot dry weight
Dicot - Tomato	EC_{25} = 0.14 (lb ai/acre) - shoot dry weight
Monocot - Corn	EC_{25} > 0.23 (lb ai/acre) - all endpoints
Monocot - Oat	EC_{25} = 0.15 (lb ai/acre) - shoot dry weight
Monocot - Onion	EC_{25} > 0.23 (lb ai/acre) - all endpoints
Monocot - Ryegrass	EC_{25} = 0.084 (lb ai/acre) - all endpoints
Dicot - White Mustard	EC_{25} > 0.31 (lb ai/acre) - all endpoints
Dicot - Veletleaf	EC_{25} > 0.31 (lb ai/acre) - all endpoints
Dicot -	

Sugar Beet	EC_{25} > 0.31 (lb ai/acre) - all endpoints
Dicot - Soybean	EC_{25} > 0.31 (lb ai/acre) - all endpoints
Dicot - Rape	EC_{25} > 0.31 (lb ai/acre) - all endpoints
Monocot - Purple Nutsedge	EC_{25} > 0.31 (lb ai/acre) - all endpoints
Monocot - Corn	EC_{25} > 0.19 (lb ai/acre) - phytotoxicity symptom

Vegetative Vigor

Dicot - White Mustard	EC_{25} > 0.31 (lb ai/acre) - all endpoints
Dicot - Veletleaf	EC_{25} > 0.31 (lb ai/acre) - all endpoints
Dicot - Sugar Beet	EC_{25} > 0.31 (lb ai/acre) - all endpoints
Dicot - Soybean	EC_{25} > 0.31 (lb ai/acre) - all endpoints
Dicot - Rape	EC_{25} > 0.31 (lb ai/acre) - all endpoints
Dicot - Teaweed	EC_{25} > 0.31 (lb ai/acre) - all endpoints
Monocot - corn	EC_{25} = 0.002 (lb ai/acre) - dry weight

Non-target Aquatic Plant Toxicity (Tier II):

Vascular Plants

Duckweed *Lemna gibba*	EC_{50} = 2.6 ppm ai

Nonvascular Plants

Green algae *Kirchneria subcapitata**	EC_{50} = 7.7 ppm ai

Formerly Selenastrum capricornutum

Green algae

Kirchneria subcapitata	EC_{50} > 5.1 ppm ai
Marine diatom *Skeletonema costatum*	EC_{50} = 39 ppm ai
Freshwater diatom *Navicula*	
pelliculosa	EC_{50} = 52 ppm ai
Blue-green algae *Anabaena flos-aquae*	EC_{50} > 175 ppm

Tralkoxydim was shown to be practically non-toxic to birds, slightly toxic to small mammals, practically non-toxic to bees and other beneficial insects, and practically non-toxic to fresh water invertebrates. For terrestrial plants, tomato is the most sensitive dicot and ryegrass the most sensitive monocot and corn the most sensitive monocot in the vegetative vigor tests. For aquatic plants, green algae was the most sensitive nonvascular species and duckweed the most sensitive vascular species.

The primary risk resulting from the application of Tralkoxydim on wheat and barley growing areas is non-target plants exposed to drift from aerial application. There are no acute or chronic risk to non-target endangered fish, birds, aquatic invertebrates, or aquatic plants. Zeneca Ag Products is participating in the Endangered Species Task Force that is gathering information on the locations of all endangered species relative to areas used for agriculture. Zeneca is also a member of the Industry-EPA Spray Drift Task Force that is working to reduce the risk to non-target organisms from spray drift.

To reduce the risk to non-target plants the following statements are required on the label of end use products:

> Avoid spray drift. Do not apply when weather conditions may cause drift. Do not allow this product to drift onto Non-target areas. Drift may result injury to adjacent crops and vegetation. To avoid spray drift, do not apply aerially when

wind speed is greater than 10 mph or during periods of temperature inversion.

The following statement must appear in the Environmental Hazards section of the label of end use products:

Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Drift and runoff may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water by disposal of waste waters.

The following statement must appear in the Environmental Hazards section of the label of end use products:

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the Environmental Protection Agency.

ENVIRONMENTAL CHARACTERISTICS

Tralkoxydim hydrolysis is pH dependent with calculated half-lives of 6.3 days at pH 5, 114 days at pH 7 and 1,594 days at pH 9. Tralkoxydim is not persistent to photodegradation in water with calculated half-life was 19.3 days. On soil surfaces, tralkoxydim rapidly photolyzed with a corrected half-life of 2.4 days.

Tralkoxydim rapidly degraded in the aerobic United Kingdom soils. The major degradates were tralkoxydim acid (Compound 8) and Compound 17. Compound 8 reached a maximum concentration of 12.5% of by 7-15 days posttreatment and declined to non-detectable concentrations by 30-65 days posttreatment. Compound 17 increased to 17.2% by 3-15 days and declined to 1 - 2.9% by the end of the study (94 days). For anaerobic aquatic metabolism tralkoxydim half-lives ranged from 47 to 115 days, and were not used in risk assessment because of this variation. Soil

adsorption/desorption data indicate that tralkoxydim and its degradates are very mobile in most of the tested soils. In supplemental field dissipations studies in Illinois, Montana, Washington and Canada, the parent compound dissipated rapidly with half-lives from < 1 to 35 days.

Tralkoxydim residues bioaccumulation was relatively low in Bluegill Sunfish exposed in a flow-through system for 28 days.

Based on PRIZM-EXAMS and SCI-GROW2 computer models, concentrations of tralkoxydim in surface water and ground water are expected to be 0.528 µg/L and 0.019 µg/L, respectively.

Specific labeling for ground and surface water are not needed at this time.

TOLERANCE ASSESSMENT

Tolerances are established for residues of the herbicide, tralkoxydim, 2-(Cyclohexen-1-one, 2-[1-(ethoxyimino)propyl]-3-hydroxy-5-(2,4,6-trimethylphenyl)-(9Cl) in or on the raw agricultural commodities: barley grain, barley hay, wheat grain and wheat hay at 0.02 ppm, and barley straw, wheat forage and wheat straw at 0.05 ppm

AGGREGATE EXPOSURES

In examining aggregate exposure, Food Quality Protection Act (FQPA) directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures. The primary non-food sources of exposure the Agency looks at include drinking water (whether from groundwater or surface water), and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

1. From Food and Feed Uses

The Reference Dose (RfD) for tralkoxydim is 0.005 mg/kg/day. This value is based on the systemic NOAEL of 0.5 mg/kg/day in the dog chronic feeding study with a 100-fold uncertainty factor to account for interspecies extrapolation (10x) and intraspecies variability (10x).

A DEEM chronic exposure analysis was conducted using tolerance levels for wheat and barley and assuming that 100 percent of the crop is treated to estimate dietary exposure for the general population and 22 subgroups. The chronic analysis showed that exposures from tolerance level residues in or on wheat and barley for children 1-6 years old (the subgroup with the highest exposure) would be 1.4% of the Reference Dose (RfD). The exposure for the general U.S. population would be less than 1% of the RfD.

An acute dietary risk assessment is required for tralkoxydim based on the NOAEL of 30 mg/kg/day from the rat developmental study. The acute dietary analysis using the DEEM computer program estimates that the distribution of single-day exposures utilizes 0.02 percent of acute RfD.

A lifetime dietary carcinogenicity exposure analysis was conducted for tralkoxydim using the proposed tolerances along with the assumption of 100% of the crop treated and a Q* of 1.68 x 10^{-2} $(mg/kg/day)^{-1}$. A lifetime risk exposure analysis was also conducted using the DEEM computer analysis. The estimated cancer risk (5 x 10^{-7}) is less than the level that the Agency usually considers for negligible cancer risk estimates.

2. From Potable Water

Drinking water acute estimated environmental concentration (EECs) for surface water (parent tralkoxydim) was calculated by PRIZM-EXAMS computer models to be an average of 4.3 parts per billion (ppb)and 0.528 ppb for chronic EEC. The EEC for ground water based on the computer model SCI-GROW2 were calculated to be an average of 0.016 ppb. The drinking water level of comparison (DWLOC) for acute exposure to tralkoxydim in drinking water calculated for females 13+ years old was 9000 ppb. EPA's acute drinking water level of comparison is well above the estimated

exposures for tralkoxydim in water for the subgroup of concern.

The drinking water level of comparison (DWLOC) for chronic exposure to tralkoxydim in drinking water calculated for U.S. population was 150 ppb and for children (1 - 6 years old) the DWLOC was 50 ppb. EPA's chronic drinking water level of comparison for the U.S. population and the subgroup of concern is above the estimated exposures for tralkoxydim in water of 0.528 ppb for surface water and 0.016 ppb for groundwater.

A DWLOC for cancer was calculated as 1 ppb. The EEC in surface water and groundwater for tralkoxydim are 0.528 ppb and 0.016 ppb, respectively. The model exposure estimates are less than the cancer DWLOC.

EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to tralkoxydim residues. The nature of the residue in plants is adequately understood for the purposes of this time-limited tolerance. Based on the results of animal metabolism studies, it is unlikely that significant residues would occur in secondary animal commodities from this use.

3. From Non-Dietary Uses

There are no non-food uses of tralkoxydim registered. No non-dietary exposures are expected for the general population.

4. Cumulative Exposure to Substances with Common Mechanism of Toxicity

Tralkoxydim is structurally a cyclohexanedione. For tralkoxydim, EPA has not yet conducted a detailed review of common mechanisms to determine whether it is appropriate, or how to include this chemical in a cumulative risk assessment. After EPA develops a methodology to apply common mechanism of toxicity issues to risk assessments, the Agency will develop a process (either as part of the periodic review of pesticides or otherwise) to reexamine these tolerance decisions. The Agency has determined that there are no metabolites of toxicological concern associated with tralkoxydim. Therefore, EPA has not assumed that tralkoxydim has a common mechanism of toxicity with other substances.

EPA is required to develop a screening program to determine whether certain substances (including all pesticides and inerts) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other

effect...." The Agency is currently working with interested stakeholders, including other government agencies, public interest groups, industry and research scientists in developing a screening and testing program and a priority setting scheme to implement this program. Congress has allowed 3 years from the passage of FQPA (August 3, 1999) to implement this program. At that time, EPA may require further testing of this active ingredient and end use products for endocrine disrupter effects.

OCCUPATIONAL EXPOSURE

EPA has concluded using the NOAEL of 30 mg/kg/day from the rat developmental study and that the Margin of Exposure (MOE) for occupational exposure range between 1000 and 25500 for the highest dermal and inhalation exposures. A MOE of 100 or higher is accepted as showing an adequate margin of safety for occupational exposure. The available evidence does not indicate any evidence of significant toxicity from short-term dermal, intermediate term dermal, or inhalation routes of exposure.

A cancer occupational risk assessment was conducted and the base line total risk for occupational exposure was calculated to range from 1.1×10^{-5} to 1.0×10^{-7}. This is a level which the Agency generally considers to be acceptable for excess life-time occupational cancer risk.

SUMMARY OF DATA GAPS

1. Oncogenicity study - Second Species [Guideline #83-2]

2. Aerobic Soil Metabolism using representative U.S. soils [Guideline #162-1]

3. Aerobic Aquatic Metabolism with emphasis on degradates tralkoxydim acid (Compound 8), Compound 3 and Compound 17 [Guideline #162-4]

4. Leaching-Adsorption-Desorption Data for the degradate Compound 3 [Guideline #163-1]

5. Terrestrial Field Dissipation [Guideline #164-1]

6. Freshwater Fish LC_{50} for degradate tralkoxydim acid [Guideline #72-1]

7. Freshwater Invertebrate LC_{50} for degradate tralkoxydim acid [Guideline #72-2]

PUBLIC INTEREST FINDING

Achieve 40 DG Herbicide and Achieve 80 DG Herbicide are effective at controlling certain grass weeds that are common through out wheat and barley production areas. Due to lower use rates and the alternative herbicides that will be replaced, the total herbicide volume applied to wheat and barley would be reduced.

GOVERNMENT PERFORMANCE AND RESULTS ACT (GPRA)

Registering tralkoxydim will meet the objectives of GPRA title 3.1.1 by assuring new pesticides that enter the market are safe for humans and the environment and title 4.1.2 by reducing environmental exposure to herbicides.

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DISCLAIMER: The information presented in this Pesticide Fact Sheet is for informational purposes only and may not be used to

fill data requirements for pesticide registration and reregistration.